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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,245	09/10/2003	M. Ishaq Haider	P-5834	3493
26253	7590	09/01/2005	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/659,245	HAIDER ET AL.
	Examiner	Art Unit
	Kevin C. Sirmons	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 June 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 40-49 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9 and 40-49 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Specification (2nd Time)

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) See claim 40.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: means for limiting; pressure-generating means.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pressure-generating means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 40-49 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Willis U.S. Pat. No. 6,314,317.

Wills discloses a needle for delivery of a substance to the skin of a patient comprising: a shaft having a wall defining a longitudinally extending bore, a first end that is open to receive a substance in the bore, a second end adapted to penetrate skin of a subject (fig. 2), and a penetration length extending from the skin engaging surface to a distal tip of the second end of less than about 4.5 mm (col. 6, lines 50-54); and at least one side port extending through the wall and communicating with the bore, the side port being arranged about 0.025 mm to about 3 mm (fig. 2 and from the skin engaging surface, wherein when the needle is fully penetrated into the skin, the skin engaging surface contacts the skin, and the substance exits the side port directly into the skin (fig. 2); a diameter (fig. 2); Furthermore, the device of Wills is fully capable of performing the function as set forth in the claim 1; as to claim 2-6, (fig. 2); as to claim 9, (col. 6, lines 50-54); as to claims 40-49, (see above rejections and entire specification).

It may not be clear to some whether or not Wills discloses the various ranges disclosed in the claims. However, it is the examiner's position that the various ranges taught by applicant, and clearly disclosed and encompassed by Wills, would be clearly understood by someone of ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wills to vary the various dimensions as set forth in the claims since Wills teaches that the various ranges can be changed and/or varied. Furthermore, applicant lacks criticality for the various ranges and it is clear that the device of Wills could perform like the device of applicant.

Response to Arguments

The examiner has reviewed paragraphs 40 and 45 that allege to set forth representative structure, materials and acts, which perform the function recited in the claim elements. The specification clearly does not set forth representative structure, materials and acts, which perform the function, recited in the claim elements. Therefore, the objection is maintained.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., size of the ports and port which are continuously open to flow) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note: less than 5 psi includes anything from 0 psi to 5 psi, which the device of Willis is fully capable of performing the function.

In response to applicant's arguments, the recitation a drug delivery device for intradermal delivery has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Note: The claims as now amended do not have a specific size and pressure limitation. The alleged specific size and pressure limitations are clearly taught and suggested by Willis and anyone of ordinary skill in the art. The Examiner may absolutely positively rely on "the level of skill in the art" to provide suggestion to make modification to the Willis device especially when it would not destroy the device of Willis and when applicant has not disclosed criticality for the dimensions claimed and functionally recited.

Note: Applicant's claims contain a substantial amount of functional language. Applicant may want to strongly consider adding structure to overcome the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Primary Examiner
Art Unit 3763

